DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 27 2006

Ms. Karen Anderson, MT (ASCP)
Director of Customer Support
Sebia, Inc.
400-1705 Corporate Drive
Norcross, Georgia 30093

Re: k052291
Trade/Device Name: Capillarys Hemoglobin (E), PN 2007
Regulation Number: 21 CFR § 864.7515
Regulation Name: Abnormal Hemoglobin Assay
Regulatory Class: II
Product Code: GKA
Dated: May 15, 2006
Received: May 17, 2006

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K052991**

Device Name: **CAPILLARYS HEMOGLOBIN(E) , PN 2007**

Indications for Use:

The CAPILLARYS HEMOGLOBIN(E) kit is designed for the detection and the characterization of hemoglobins in human blood with the Sebia CAPILLARYS system, for capillary electrophoresis. The CAPILLARYS performs all procedural sequences automatically to obtain a hemoglobin profile. The CAPILLARYS system automatically mixes the blood sample with hemolysing solution The hemoglobins, separated in silica capillaries, are directly detected by their absorbance at 415 nm. The electrophoregrams are evaluated visually for the pattern abnormalities. Direct detection of the hemoglobins provides relative quantification of individual hemoglobin fraction of the normal hemoglobin fractions A, A2, F and for the detection of major hemoglobin variants as S, C , E and D using Capillarys electrophoresis

For in vitro diagnostic use

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052991